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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,761	03/10/2005	Alan Crossman	184.SUSWO	3221
22462 7590 09/15/2008 GATES & COOPER LLP HOWARD HUGHES CENTER 6701 CENTER DRIVE WEST, SUITE 1050 LOS ANGELES, CA 90045				
			EXAMINER JAVANMARD, SAHAR	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 09/15/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/527,761

**Applicant(s)**

CROSSMAN ET AL.

**Examiner**

SAHAR JAVANMARD

**Art Unit**

1617

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14, 15, 19, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 19, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

This Office Action is in response to applicant's arguments filed on 10/09/2007. Claim(s) 14-15, 19, and 25-26 are pending. Claim(s) 14 has been amended. Claims 16-18 and 20-24 have been cancelled. Claim(s) 14-15, 19, and 25-26 are examined herein.

### ***Response to Arguments***

Applicant's arguments with respect to the 112 1<sup>st</sup> rejection over claims 14-26 has been fully considered and is persuasive. The rejection is hereby withdrawn.

In view of Applicant's cancellation of claim 23, the 112 2<sup>nd</sup> rejection is moot and the rejection is hereby withdrawn.

Applicant's arguments with respect to the 102(b) rejection of claims 14-18 and 23 as being anticipated over Shank et al. (WO 00/61138) has been fully considered but is not persuasive as Applicant is now arguing based on amended claims. Since Applicant has amended/cancelled the claims, said rejection is hereby withdrawn.

Applicant's arguments with respect to the 102(b) rejection of claims 14, 21, 22, and 24 as being anticipated over Dursun et al. (*Canadian Journal of Psychiatry*, 2000) has been fully considered but is not persuasive as Applicant is now arguing based on amended claims. Since Applicant has amended/cancelled the claims, said rejection is hereby withdrawn.

Applicant's arguments with respect to the 103(a) rejection of claims 19, 20, 25, and 26 as being unpatentable over Dursun et al. (*Canadian Journal of Psychiatry*, 2000) in view of Wolters (*CMAJ*, 1989) has been fully considered but is not persuasive as Applicant is now arguing based on amended claims. Since Applicant has amended/cancelled the claims, said rejection is hereby withdrawn.

A modified 103 rejection as necessitated by amendment is presented in the Office Action below.

### ***Objections***

Applicants have inadvertently left out the definition of R<sub>1</sub> in claim 14 and the specification. Appropriate action is required.

Claims 25 and 26 are dependent on a cancelled claim. Appropriate action is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dursun et al. (Canadian Journal of Psychiatry, 2000) and <http://www.answers.com/topic/dyskinesia>.

Dursun discloses a study whereby a 29-year-old male diagnosed with chronic paranoid schizophrenia is treated with clozapine and responds positively to the medication. The patient however develops some side effects including myoclonic jerks in both hands, arms, and shoulders, in addition to excessive weight gain (column 1, paragraph 1). The same patient is then administered topiramate which showed improvement in his mood and complete improvement of his myoclonic jerks (column, paragraph 3).

Dursun does not specifically teach dyskinesia.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have considered the myoclonic jerks observed, arising from the administration of clozapine, as a type of dyskinesia. According to its definition, as

evidenced by <http://www.answers.com/topic/dyskinesia>, dyskinesias are excessive abnormal movements that are involuntary. There are several different types of dyskinesias, and each has different clinical symptoms, causes and treatments. The dyskinesias can be categorized as chorea, dystonia, myoclonus, tremor, and paroxysmal tardive (late-onset type). Thus, taking into consideration what "dyskinesia" encompasses, one would have, with a reasonable degree of certainty, known that by administering the topiramate, that the improvement in myoclonic jerks that was observed was in fact treating a type of dyskinesia.

Claims 19, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dursun et al. (Canadian Journal of Psychiatry, 2000) as applied to claims 14 and 15 above in view of Wolters et al. (CMAJ, 1989).

Dursun is discussed above.

Dursun teaches treating a neurodegenerative disease with a therapeutic agent that treats the symptoms of that particular disorder, specifically treating schizophrenia with clozapine and further administering an additional agent to treat the dyskinesia-like side effects with topiramate.

Dursun does not teach the dyskinesia specifically as it applies to Parkinson's disease and further does not teach the side effect arising from dopamine replacement

therapy (ie, group consisting of ropinirole, pramipexole, cabergoline, bromocriptine, lisuride, pergolide, L-DOPA and apomorphine).

Wolters teaches that L-DOPA is an effective treatment in most patients with Parkinson's disease, however, associated with L-DOPA are adverse peripheral or central reactions. Central reactions comprise of psychiatric disorders and dyskinesia (page 508-509, "Dopamine precursor" section).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed topiramate to treat the dyskinesia-like side effects caused by clozapine as taught by Dursun to have also used topiramate to treat the dyskinesia-like side effects caused by L-DOPA to treat Parkinson's disease as taught by Wolters. Although Dursun teaches treating schizophrenia and Wolters teaches treating Parkinson's disease, the drugs administered to treat each disease, both neurodegenerative in nature, results in dyskinesia. Thus it would be obvious to use the same drug (i.e. topiramate) to treat the same side effect (i.e. dyskinesia) regardless of what the nature of the disease is.

### ***Conclusion***

Claims 14-15, 19, and 25-26 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617